Research Article

Ethical issues in qualitative research: challenges and options

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Abstract

Background: We have been conducting workshops on "Qualitative Methods in Health Research" since last 5 years for health professionals in India.

Objective: To explore the concerns and suggestions of the participants during their learning of ethical issues in qualitative research in a workshop setting.

Materials and Methods: We obtained responses in an interactive session on ethical issues in qualitative research from a group of newly trained participants in workshops conducted in the years 2011 (n = 13) and 2013 (n = 30). A summative manual content analysis was done to identify themes generated. The results were compiled by two authors in which one was trained in qualitative research and another was trained in ethics in biomedical research. The discussion was developed in consensus.

Result: The ethical challenges in qualitative research that emerged were (1) ensuring confidentiality, (2) selecting a tool and an approach for studying sensitive topics, (3) developing a consent form for a flexible interview, (4) addressing risks, (5) ethical reviewing of qualitative research proposals, and (6) publishing qualitative research findings. Participants suggested the need for training of researchers and ethics committee members in qualitative research methods.

Conclusion: The findings may help in developing instructional design for ethics education in qualitative research and stimulate the generation of separate guidelines for the conduct of qualitative research in the future, in our country.

KEY WORDS: Qualitative research, ethics, Institutional Ethics Committees, India

Introduction

Globally, qualitative research is becoming more common, both alone and paired with quantitative research, in clinical medicine and health service research.[1] There are considerable differences between qualitative and quantitative research with respect to philosophical assumptions, research questions, methods, analysis, and its reporting, resulting in certain unique ethical issues [Table 1]. There appears to be a paucity of literature and discussion on ethics in qualitative research in India. Recently, in our country, there is a growing interest among researchers, mostly trained in quantitative research methods, to undertake qualitative research as well. These researchers, therefore, lack orientation of differences between qualitative and quantitative research leading to difficulties of understanding of ethical issues of qualitative research. Hence, this study was conducted to explore the concerns and suggestions of the participants during their learning of ethical issues in qualitative research in a workshop setting.

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Materials and Methods

Setting

We have conducted two 5-day workshops, one each in the years 2011 and 2013, on "Qualitative Methods in Health

Table 1: Differences between quantitative and qualitative research leading to challenges in ethics approval process of qualitative research proposals

Quantitative research	Qualitative research	Challenges in ethics approval process of qualitative research proposals
Surveys, structured interviews and observations, and reviews of records or documents *for numeric information*	Focus group discussions, in-depth interviews, and reviews of documents *for types of themes or developing new understanding*	Ethics committees call for structured, predetermined, and a logically prestated objective and design, thus resulting in conflicts with the flexible nature of qualitative research (e.g., discussions and interviews of qualitative research evolve through participant responses)
Primarily *deductive* process used to test prespecified concepts, constructs, and hypotheses that make up a theory	Primarily *inductive* process used to generate theory or hypotheses	A prestated hypothesis is required for the ethics application while qualitative research is frequently used to generate a hypothesis
Quantitative research is a *forward-moving process*, where planning follows data collection, analysis, results, and reporting	Qualitative research may *be a nonlinear process* where researchers may need to move back and forth at any steps	Ethics committees mandate estimated sample size, sampling frame, and selection clearly stated before start of research while qualitative research design approves changes in sampling, sample size, and questions in interview tools as the process evolves
The interpretation of results of quantitative research is validated by their generalizability and objectivity. Thus a large sample size and probability sampling are required	As qualitative research examines subjective responses of participants, the interpretation and understanding of the issues are not generalizable. Hence, small sample sizes and non-probability sampling are accepted	Lack of generalizability, small sample sizes, and non-probability sampling are less likely to be approved by the ethics committees
Number-based and statistical tests are applied for analysis	*Text-based* and requires content analysis. No statistical test can be applied	Analysis of results in qualitative research involves examination of subjective experiences and therefore conventional statistical methods do not apply. This may raise questions during the ethics approval process
Ethical guidelines are well worked out for quantitative researchers	*Ethical guidelines* do not provide much guidance to qualitative researchers	The current guidelines are more suited for quantitative research rather than qualitative research

Research" for health professionals in India, by faculty trained in qualitative research.

Selection of the Participants

The participants were selected on a *first-come-first serve* basis. We had 13 participants in the year 2011 and 30 participants in the year 2013. These 43 participants had varying backgrounds, such as faculty in community medicine (16), postgraduates in community medicine (19), faculty in obstetrics and gynecology (3), social work expert (1), faculty in forensic medicine (1), psychiatrist (1), nursing (1), and physiotherapy (1).

Clearance from the Ethics Committee

Before the conduct of workshop events, the workshop program, session plan, and evaluation plan of all sessions were shared with our institutional ethics committee and the ethics clearance was obtained. The informed consent was obtained from all the participants on Day 1 of the workshop.

Session on Ethics in the Years 2011 and 2013

During initial 4 days, the emphasis was given on research questions, methods, analysis, and interpretation as related to qualitative research methods, through interactive sessions and hands-on exercises. In 2013, we had an additional elaborate session on various approaches in qualitative research, such as phenomenology, ethnography, and grounded theory approach. On the fifth day, a session on ethics in qualitative research was conducted in both years. Participants were first orientated to the ethical principles as enunciated in Ethical Guidelines for Biomedical research on Human Participants by the Indian Council of Medical Research (ICMR).[2] Later, each participant was given a plain paper to write down (1) ethical issues they are facing or anticipate facing while doing qualitative research and (2) suggest some guidance to address these issues. This activity was followed by an individual presentation and group reflections on it. This was followed by debriefing on general ethical principles and specific ethical issues relating to qualitative research. A case scenario for

Table 2: Content analysis of responses from the workshop participants in the year 2011 (n = 13)

Themes	Responses from the participants	Solutions
Study topics	• Sensitive topics have the potential to cause emotional disturbance to the participants (1) • Addressing the sensitive issues (sex-related matters, homosexual youths, mental health problems, diagnosed for HIV, cancer or recent death in a family, interviews at old age homes, victims of violence) (2)	For sensitive topics, methods such as individual interviews may be adopted. For example, FGDs are typically best used for topics that are less sensitive, where loss of confidentiality is not a substantial risk
Study tool	• IDIs are cumbersome for the participants • Revelation of somebody's personal information in group interview (2) • Conflicts in FGDs (1)	Select methods that avoid sharing of personal information with others
Consent forms	• Difficult to frame informed consent for qualitative study with open-ended and probing questions (unstructured interviews)	Explain the nature of the interview to the participants
Confidentiality and privacy	• Confidentiality (as the number of participants are few) (6)	Stop the interview, if the respondent gets disturbed. Make every effort to report results in a way that protects participant confidentiality
Respondent-related issues	• The mental stress on the respondent due to a long interview with probing (2)	Plan ahead by providing adequate referral services to participants and have a crisis management plan in place for participants and staff members
Interviewer-related issues	• Interviewer's experience is a matter of concern • It may mentally disturb the respondents (due to unplanned blunt probe) • Wrong way of asking questions • Lack of interviewers' sensitivity to participants' feelings • Misinterpretation by the interviewer and recorder (2)	Interviewers should be formally trained in qualitative research methods. When in doubt, stop data collection and make a report to the IRB and ask for guidance
Related to the ethics committee	• Difficult to convince ethics committee members, especially when the researcher is young and less experienced (2) • Poor orientation of research/ethics committee members in qualitative research	Ensure sensitization of research/ethics committee members in qualitative research methods

FGD, focus group discussion; IDI, in-depth interview; IRB, Institutional Review Board.

Table 3: Content analysis of responses from the workshop participants in the year 2013 (n = 30)

Themes	Responses from the participants	Suggested solutions
Study topics	• Research on sensitive topics (3)	The researcher should be trained and care in probing questions. Participants are fully informed about the nature of the study. Researcher should be empathetic
Study tool	• Ensuring privacy in FGDs (2) • Risk minimization	Select a method, which does not leak personal information to others, says the use of IDIs. Participants are informed not to reveal personal information in FGDs. Participants should be informed the ground rules in FGD session. Seek guidance from the expert while designing the study
Consent form	• The time-consuming nature of obtaining consent • Fear of more refusal, designing a consent form • Participants fear to lose confidentiality by signing the consent form • Withdrawal of consent during the process of the study • How to obtain the consent? (7) • Obtaining (ongoing) consent may not be possible, e.g., ethnography (2) • Apprehension of some populations in rural setting to sign the document • Voluntariness and informed consent-related issues (4)	Contact more respondents, keeping in mind the refusal, and provide proper explanation for the purpose of study. Consider waiver for written consent in some situations. Keep on taking ongoing consent and ensure not to hurt sentiments. Consent process should be ongoing (6). The informal nature of the study should be informed to the participants. Explain the nature of the study to the participants
Privacy and confidentiality	• Communicating with the people having stigmatized illness or conditions • Research on sensitive topics • Ensuring privacy and confidentiality in phenomenological research • Ensuring privacy and confidentiality while using photos and videos • Privacy and confidentiality (14)	Try to contact respondents in a health-care facility. Contact the respondent in advance if a home visit is planned. The initial rapport building should be done. Inform the participants about the sensitive nature of the study
Respondent-related issues	• Emotional trauma/disturbance to the respondent (5) • Loss of income (If the participants are daily waged workers) (2) • Is there any direct benefit to study participants? • Minimizing the risk to the participants • Obtaining consent while doing qualitative research with/on children • Exploitation of vulnerable groups	Inform the nature of study\interview prior to its conduct. Seek the help of a professional counselor for counseling services (4). Ensure compensation, study design may be modified to minimize the risk, rapport building with the local community. Obtain necessary permissions from the local authorities
Interviewer-related issues	• Subjective interpretation of information • Professional competence (15)	More than one researcher is involved in analysis of data. Training and refresher training for the researchers (14)
Related to ethics committee members	• Institutional Ethics Committees (IEC) members not equipped to deal with the proposals on qualitative research methods	The ethics committee should have a member having anthropology or social Science background while reviewing such proposals ICMR should bring out tailor made guidelines on ethics in qualitative research is needed. “Ethics of virtue” may be the guiding principle for guidelines
Publication	• Permission to publish potentially stigmatizing personal information (2) • Informal communication allows more rich information • How to publish the sensitive information maintaining the confidentiality?	Avoid reporting of personal details. If required, the context may be changed. Consent for publication may be obtained after the information is obtained (2). Prepublication consent can be obtained

FGD, focus group discussion; ICMR, Indian Council of Medical Research; IDI, in-depth interview.

discussion of a sensitive topic in focus group discussion (FGD) was then discussed with the group highlighting possible risks to the participants, risk minimization strategies, and also the concerns the ethics committees would be addressing. After this the session closed with the workshop participants being given an opportunity to modify their earlier written responses in the light of new knowledge that they have been exposed.

Analysis

We analyzed the data of the two workshops separately. The manual summative content analysis of final responses noted on the plain papers was carried out.[3] The unit of analysis was statements. The codes were generated from the text itself. The statements with similar codes and meaning were brought together and tagged with a theme. This analysis was done by first author, who is trained in qualitative research methods and he was the main resource person in the workshop. The results were then shared with Ramalingam Sankaran, who is trained in ethics in biomedical research, and the results and discussion were developed in consensus. Any disagreement between the two was resolved by face-to-face discussion.

Results

The content analysis of responses from 13 and 30 participants in the workshop on Qualitative Research Methods, held in the years 2011 and 2013, generated six and seven themes, respectively. Themes generated from the participants in the years 2011 and 2013 were similar, except for one additional theme on "publication issues" in the year 2013. Hence, these themes are presented separately in Tables 2 and 3, but are described together below and the statements in italics indicate participants' suggestions on ways to address ethical issues in qualitative research.

Study Topic

According to the participants, exploration of sensitive topics (such as patients with HIV; homosexual youths; patients with chronic diseases such as cancer; those with mental health problem; and victims of violence, child abuse, and elder abuse) has a potential to cause emotional disturbance in the respondents. There is a risk of break in confidentiality.

Participants suggested using data collection method that avoids breaching in confidentiality of the participants. For example, instead of FGDs, in-depth interviews (IDIs) may be conducted. In case of emotional disturbance, further interview should be stopped and counseling and follow-up care should be provided or ensured. Participants felt that the qualitative researchers should be empathetic and trained enough to probe in such sensitive and personal areas.

Study Tool

Participants felt that in FGDs, there may be conflicts due to difference in opinions and IDIs are sometimes cumbersome and exhaustive.

Participants suggested selecting a tool that avoids exploration of personal information in groups, if the topic is sensitive in nature or has some stigma attached to it. Respondents should be explained the nature of the IDI or FGD in advance. In case of FGDs, the ground rule of not revealing someone's personal information should be emphasized. Participants suggested seeking guidance of experts (in selecting the study tool) while designing the research proposal.

Voluntariness and Informed Consent

Participants wanted to know how to design a consent form for a qualitative research. They had various concerns such as (1) high refusal to consent for participation, (2) time-consuming nature, (3) withdrawal of consent during the process of study, (4) participants' apprehension to lose the confidentiality by signing the consent form, and (5) difficulty in obtaining informed consent in ethnographic research on observations in public places.

Participants suggested contacting more respondents keeping in mind the expected number of refusals. The consent taking process should be ongoing and respondents of the study should be completely informed about the nature of the study. Individual consent may be waived in some situations such as ethnographic studies in public settings.

Privacy and Confidentiality

Participants had a concern about privacy and confidentiality due to (1) sensitive topics, (2) use of photographs and videos, (3) phenomenological designs where lived-in personal experiences are explored, and (4) the small sample size that may compromise confidentiality.

Participants suggested contacting respondents in a health-care facility (rather than in their familiar surroundings). It has been suggested to take permission and appointment from the respondents, if home visits or contact required for further information. There has to be a phase of the initial rapport building before the phase of data collection. Respondents should be informed about the sensitive nature of the study. Participants responded to ensure confidentiality during data collection, analysis, and reporting.

Respondent-Related Issues

Participants felt that the inquiry in qualitative research may lead to (1) psychological disturbance in the respondents, (2) loss of income for daily wagers because of the long duration of interviews, and (3) challenges in research in vulnerable groups.

Participants suggested making available counseling services in case of potentially disturbing interviews on sensitive study topics. They suggested stopping the interview and ensuring referral services and follow-up, if respondent gets disturbed during the interview process. The risk may be minimized by altering the study design, which would protect the privacy and confidentiality of the participants. Participants should be fully informed about the nature of the study and the rapport building should be ensured before the conduct of the research or interviews.

Interviewer-Related Issues

Experience of interviewing in qualitative research is crucial to avoid wrong framing of questions and disturbing probing. There is also a risk of misinterpretation of information. Participants expressed the need for professional competence among the researchers using qualitative research methods.

Participants suggested that the qualitative researchers must be a qualified or trained person in qualitative research methods. They suggested involving more than one researcher in the interpretation of data and emphasized the need for the participant validation of the results. Hence, they suggested the need for training and refresher training for the researchers.

Ethics and Research Committee Members

Participants felt that due to lack of orientation to qualitative research methods, ethics committees might find it difficult to review proposals on qualitative research methods.

There is a need for sensitization of research/ethics committee members in the nature of qualitative research methods and as how to review qualitative research proposals. Participants suggested involving a member in the ethics committee from a sociological/anthropological background while reviewing proposals on qualitative research. Some participants felt that the ICMR should develop the guidelines for the conduct of qualitative research in the health sector.

Publication Issues

Participants expressed the issues related to publication of potentially stigmatizing personal and sensitive information.

It has been suggested to avoid the reporting of personal details or change the context if required. The results should be shared with the participants and prepublication consent should be obtained.

Discussion

This study was conducted to explore the concerns and suggestions of the participants during their learning of ethical issues in qualitative research in a workshop setting. The ethical challenges that emerged were as follows: (1) ensuring confidentiality, (2) selecting a tool and approach for studying sensitive topics, (3) developing a consent form for a flexible interview, (4) addressing risks, (5) ethical reviewing of qualitative research proposals, and (6) publishing ethics. Participants suggested the need for training of researchers and ethics committee members in qualitative research methods.

Confidentiality as defined by ICMR mandates that no details about identity of human participants should be revealed, which would result in disclosure of their identity. In keeping with this spirit, our participants also suggested that the data collection tools in qualitative research should not cause any breach in confidentiality. In this connection, they felt that IDIs are preferable to FGDs, particularly for sensitive topics.[4]

However, it needs to be pointed out that even FGDs, particularly those involving sensitive topics, do have certain safety features for maintaining confidentiality. The guidelines indicate that the participants desist from relating to first person experiences and adopt third person, generic narratives. IDIs may be preferable if first person narratives or deeper information is required. Equally, it is important for the moderators to be skilled in interview techniques appropriate for the chosen method.[4]

If the participants belonged to a certain group or a cult given to certain habits, identity may be guessed by others even in IDIs, and full concealment of identity may become challenging when reports are published.

Kaiser[5] has suggested an interesting "alternative approach" as opposed to conventional and dominant approaches to maintain confidentiality. This approach calls for a detailed discussion with the respondents regarding use of data and the dissemination plans. Such discussions help both the researcher as well as the participants to understand the extent of confidentiality that can be maintained, and also learn about the participants' preferences in dissemination plans. He further suggests that such discussions are held before data collection begins, as part of the initial consent process so that the participant is able to make a truly informed decision while consenting.

However, Crow et al.[6] and Morse[7] argued for such a discussion after data collection. They pointed out that stating our specific plans for data dissemination might influence what respondents say or how they behave. Discussing after data collection and prior to dissemination may also be an effective way of participant validation of what could be disseminated.

While a principlist approach favors concealment of identity as a measure of confidentiality, the qualitative researcher may have to adopt "ethics as virtue" paradigm (which draws on the notion of researcher integrity and seeks to identify the characteristics or virtues that a researcher need in order to behave in morally/ethically good ways) under certain circumstances as when an individual is in an emergency situation (e.g., minors reporting a sexual abuse). The researcher may waive the promise of confidentiality for the good of the individual or of others and search for ways to deal with emerging ethical or legal issues.[8] Although ICMR guidelines do support a breach of confidentiality under certain conditions, situations arising in qualitative research are not explicitly described or stated.[2]

The major challenge expressed by our participants regarding informed consent in qualitative research related to the difficulty of developing a consent form where the interview is based on flexible, open-ended probing questions. Very often probing in such interviews evolve based on prior responses in real time, thus making a pre-participatory, one-time, fully informed, and rigid informed consent document or process inadequate. In qualitative research settings informed consent document and process cannot be finite and clear, and will at best explain the evolving nature of the project rather than clarifying all aspects of research as is required by the quantitative research designs.

Richard and Schwartz[9] had mentioned a two-step approach to ensure that the adequate consent had been obtained: (1) participants can be asked to give a "general consent" to begin with and (2) treat consent as an ongoing process, where it is not a "once and for all" event but a "renegotiation" over time.

Apart from the mandated contents of an informed consent document, such as the purpose of research, expectations from the participant, time required, benefits and risks, voluntary nature of participation, right to refuse or withdraw, confidentiality, and contact details of the investigators, it has been suggested that providing sample probing questions may also be needed for qualitative research.[10]

Even after consenting, participants should also be given the freedom to refuse to respond to uncomfortable and sensitive questions during the interview process. The participant may be informed to bring it to notice if they experience discomfort during the interview.

In community-based qualitative research, obtaining consent could involve several steps and be time-consuming. The researchers approach the community leaders and explain the research to them. The leaders may then facilitate a community forum, where interested people can learn about the research and ask questions. Researchers might spend a week or two just talking with people one-on-one to gain their trust and understanding. In some situations, it may be necessary to obtain consent from community leaders before starting the study.[11] After obtaining initial consent, "process consent" during various stages of research, such as immediately after the interview, and before publication of data may be required.

Verbal consent has also been suggested by some for projects with minimal risk, where the loss of confidentiality is a primary risk and a signed consent form would be the only piece of identifying information for study participation.[12] In India, the ICMR guidelines do permit verbal consent when the written consent is not possible due to the sensitive nature of the projects. However, ICMR insists that researchers need to ensure documentation of the verbal consents by third-party witnesses or by audio/video recording. If retention of confidentiality in a sensitive project is the primary purpose of the verbal consent, documentation by a third-party witness or audio/video recording may be counterproductive.

Our participants felt that sometimes probing questions in interviews may cause emotional disturbance in some respondents. There should be clear protocols for dealing with distress that might be experienced by the participants.

One of the peculiar characteristics of qualitative research is that the researcher could also be at risk. Under such circumstances, it is important to consider the question of whether or not the researcher's interests need also be taken into account by the ethics committees during the risk assessment of the project. While the risk for the respondent is largely emotional, financial, or personal, the risk for the researcher could include physical harm as well. Risks can happen either during the data collection stage or, as negative publicity, after the publication. The physical harm for the researchers could arise from sensitive topics or high-risk locations. Therefore, it might be necessary for the ethics committees to bear this in mind during the review process.

The respondents felt it important for the committee members to be sensitized to the qualitative research methodologies and the ethical issues relating to them, thus facilitating a more robust appreciation of the salient features of qualitative research.

It is noteworthy that the literature supports the points raised by the participants. However, cultural differences between countries and population groups may necessitate country-specific guidelines. In this context, our findings may help in developing instructional design for ethics education in qualitative research and stimulate the generation of separate guidelines for the conduct of qualitative research in the future, in our country. We acknowledge that this study was conducted in a workshop setting with the specific objective of understanding the participants' points of view with respect to the ethics of qualitative research. In future, context-specific, field-based studies are required in our country to explore the culture–ethics interface in the context of qualitative research.

Conclusion

The findings may help in developing instructional design for ethics education in qualitative research and stimulate the generation of separate guidelines for the conduct of qualitative research in the future, in our country.

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